UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

Civil Action No. 6:11-370-JMC

UNITED STATES OF AMERICA *EX REL.* SALLY CHANDLER BALLENTINE

Plaintiff,

v.

INTERNATIONAL REHABILITATIVE SCIENCES, INC. d/b/a RS MEDICAL,

Defendant.

TO BE FILED *IN CAMERA* AND UNDER SEAL

COMPLAINT
(Jury Trial Demanded)

On behalf of the United States of America, and pursuant to the *qui tam* provisions of the Federal False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, (the "FCA"), Plaintiff and Relator, Sally Chandler Ballentine ("Relator"), files this *qui tam* Complaint against Defendant, International Rehabilitative Sciences, Inc. d/b/a RS Medical. In support thereof, Ms. Ballentine alleges as follows:

INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America pursuant to the *qui tam* provisions of the FCA, 31 U.S.C. § 3729 *et seq.*, based on false claims caused to be submitted by the Defendant that were and will continue to be submitted to Medicare, Medicaid, TRICARE (f/k/a CHAMPUS), and other government-funded health insurance plans in violation of the FCA.

2. Originally enacted in 1863, the FCA was substantially amended in 1986 by the False Claims Act Amendments and in 2009 by the Fraud Enforcement and Recovery Act. The

1986 and 2009 amendments to the FCA enhanced the Government's ability to recover losses sustained as a result of fraud against the United States.

3. The FCA has been interpreted broadly by the Courts, thereby effecting its intent "to reach all types of fraud, without qualification, that might result in financial loss to the Government." *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968).

4. The FCA provides that any person who knowingly submits or causes to be submitted to the Government a false or fraudulent claim for payment or approval is liable for a civil penalty from $5,500 up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government. 31 U.S.C. § 3729.

5. The FCA empowers a private person having information regarding a false or fraudulent claim against the Government to bring an action on the Government's behalf and to share in any recovery. 31 U.S.C. § 3730.

6. Pursuant to the FCA, Relator, Sally Chandler Ballentine, seeks to recover on behalf of the United States damages and civil penalties arising from the submission of false or fraudulent claims supported by false or misleading statements that Defendant submitted or caused to be submitted to Medicare, Medicaid, TRICARE, and other government-funded health insurance programs for payment by the United States.

7. In 1965, Congress enacted Title XVIII of the Social Security Act ("Medicare") to pay for the costs of certain health services and health care. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. See 42 U.S.C. §§ 426, 426A. Over 44 million Americans are covered by Medicare. Medicare is divided into Part A and Part B. Part A of the Medicare program authorizes payment for, among other things, medically necessary physician services and durable medical equipment ("DME").

8. The Medicaid Program, 42 U.S.C. § 1395, *et seq.* is a jointly funded, federal-state health insurance program that provides coverage for approximately 47 million Americans (including children), below a certain income level.

THE PARTIES

9. The Plaintiff/Relator, Sally Chandler Ballentine, is a citizen of the United States and a resident of the State of South Carolina. Ms. Ballentine brings this action for violations of 31 U .S .C. § 3729 *et seq*. on behalf of herself and the United States pursuant to 31 U .S .C . § 3730(b)(1) . Ms. Ballentine has personal knowledge of the Defendant's submission of false claims to the federal government as alleged herein.

10. The Relator began working for Defendant, International Rehabilitative Sciences, Inc., d/b/a RS Medical, on or about November 1, 2010, as a field service representative ("FSR").

11. The Relator was recruited to the position of FSR by Account Manager, Shay Forbes, who informed Ms. Ballentine that RS Medical had authorized her to hire a second field service representative because of a tremendous increase in her territory's business volume in South Carolina. Ms. Forbes's territory generally covered the Upstate of South Carolina (including Greenville, Spartanburg, Anderson, and Oconee Counties).

12. Ms. Ballentine accepted the position with RS Medical and received four days of sales training at RS Medical's headquarters in Vancouver, Washington during the second week of November, 2010. All of the fraudulent practices documented herein have come to the Relator's attention during just a three month period beginning in November 2010.

13. The Defendant, RS Medical, is a durable medical equipment ("DME") company headquartered in Vancouver, Washington.

14. RS Medical produces Transcutaneous Electrical Nerve Stimulator devices (TENS units), muscle stimulators, cervical traction devices, back braces, BioniCare knee devices, and other medical equipment.

15. According to its website, "RS Medical is America's leading provider of physician-prescribed home electrotherapy devices. More than 1 million patients have been treated with our stimulators and related products since the company was founded in 1990. RS Medical products are supported by the most comprehensive physician and patient services in the industry. An employee sales force of approximately 250 Account Managers serves physicians in more than 195 major metropolitan markets." (www.rsmedical.com/company.asp)

16. RS Medical conducts business throughout South Carolina through its account managers and FSRs located in Charleston, South Carolina, Greenville, South Carolina, and Greenwood, South Carolina.

JURISDICTION AND VENUE

17. This is a civil action arising under the laws of the United States to redress a violation of 31 U .S .C . §§ 3729 and 3730. As such, this Court has jurisdiction over the subject matter of this action pursuant to both 28 U.S.C. § 1331 and 31 U .S .C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to sections 3729 and 3730 of Title 31 .

18. This Court has personal jurisdiction over the Defendant pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because the Defendant has minimum contacts with the United States. Moreover, the Defendant has transacted and currently transacts business in South Carolina.

19. Venue is proper in this District and Division pursuant to 31 U .S .C. § 3732(a) because the Defendant has transacted business and currently transacts business in South Carolina, and the wrongful conduct alleged herein occurred, at least in part, within Greenville County, South Carolina.

DEFENDANT'S SCHEME TO DEFRAUD THE UNITED STATES

20. Upon information and belief, at all times relevant to this Complaint, it was a violation of federal law to submit, or cause to be submitted, a false or fraudulent claim for payment or approval by the Government.

21. Upon information and belief, at all times relevant to this Complaint, it was a violation of federal law to make, use, or cause to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government .

22. On information and belief, Medicare requires both a Certificate of Medical Necessity (CMN) and a prescription from a physician before it will pay for a TENS unit and certain other pain therapies. The prescription should be written on the physician's personalized prescription form and should include the patient's name, the description of the item, the physician's signature, and the date the physician signed the prescription.

23. At all times relevant to this Complaint, the Defendant was aware that Medicare and Medicaid would reimburse for TENS units and other pain therapies only with valid physician authorization.

24. Notwithstanding these requirements, the Defendant has repeatedly billed Medicare and Medicaid for TENS units and other pain therapies using false and fraudulent prescriptions.

25. Shortly after the Relator began work for the Defendant, her Account Manager instructed her not to bother the doctors but instead to use pre-signed, blank, photocopied prescriptions from approximately eight different doctors.

26. On information and belief, the Relator believes that some of the doctors' signatures may have been obtained initially on a legitimate form for a particular patient. After the initial use for the patient with the valid prescription, the patient's name, date, and other identifying information was later "whited out" by the Defendant's Account Manager, and the forms were then copied again and again to produce blank prescription forms with only the doctor's signature. On many of these forms, it is obvious that the patient name and date have been whited out.

27. The Account Manager or the FSR, not the doctor, would fill in the patient information, the diagnosis or ICD9 Codes, the products and supplies prescribed, usage instructions, and the date.

28. The Account Manager informed the Relator that she had learned this practice from Defendant's Account Manager of the Charleston, SC territory, and that she had used the practice for several years.

29. Each of the prescription forms contains a specific representation that the device is medically necessary. Above the doctor's signature is the statement, "In my opinion, in accordance with accepted medical practice standards, the above named patient requires the indicated device, garment and electrode pads as provided by RS Medical (dispense as written, *no substitutes allowed*), for the above diagnosis. If the patient's insurer chooses to purchase the device, I prescribe the device for indefinite use."

30. In addition to its practice of using blank prescription forms, RS Medical also routinely engages in a practice of upcoding – or adding additional equipment – to what the physician prescribes.

31. When a physician refers a patient to RS Medical, the referral forms are faxed from the physician's office to Defendant's Account Representative. For Medicare, Medicaid and TRICARE patients, RS Medical's routine practice was to add additional devices beyond those actually ordered by the doctor. RS Medical's Account Manager repeatedly instructed the Relator and the other FSR to "never let the patient leave with only one device." Instead, they were to sell or rent multiple devices to the patients who were covered by Medicare, Medicaid or TRICARE in order to help the Account Manager meet the Defendant's target sales goal each month.

32. In order to make the sales or rentals match the physicians' orders, the Defendant's Account Manager obtained user names and passwords from certain doctors' offices allowing the Defendant to log in and change the doctors' orders or make "an addendum" to the patient's medical chart without permission from the physician.

33. The Defendant determined what language they wished to add to the physician's notes and then typed those notes directly into the patient's medical record, posing as a nurse or a doctor. In addition, the Defendant's Account Manager instructed the FSRs to follow the same procedure.

34. To further assist in the fraud, the Defendant's Account Manager met with the FSRs and provided them with the log in information needed to access physicians' notes in the electronic medical records and gave specific instructions as to how the charts should be altered.

35. In one such meeting with the Relator, the Defendant's Account Manager instructed the Relator in precisely how to create an addendum in a patient's medical records that would support additional Medicare charges. The Relator's notes from that meeting contain login information for certain physicians' offices and the exact language that the Defendant instructed her to type into the addendum in order to alter the medical chart so that it will document the patient's need for additional medical devices.

36. The Defendant's consistent practice was that after receiving the original fax from the doctor's office and determining which additional equipment or devices could be provided to the patient, the FSR would call the patient to set up a meeting at the office of the referring physician. The physician would have a room set aside at his office for the RS Medical representative to meet with the patient and provide or fit the device. At this meeting between RS Medical personnel and the patient, neither the physician nor anyone from his staff would be present or participate. After the patient was provided with the equipment or devices, including any upcoded items, Defendant's Account Manager or the FSR would complete the prescription and alter the electronic medical records to match the delivery documents.

37. By way of example, on January 27, 2011, a physician ordered a single device – a "knee brace with hinges" -- for a Medicare patient who was diagnosed with osteoarthritis. That order was then faxed by the physician to the Defendant's Account Manager. The Account Manager then altered the patient's record to add a second device – a knee system stimulator. To accomplish this goal, Defendant's Account Manager entered a hand-written note into the right margin of the physician's order. The hand-written note says "Brace & Device" and then provides login information -- the user name and password for the doctor's electronic medical records system -- needed to edit the patient's chart "for addendum" to support the "Device" that

the Account Manager wanted to sell the patient. The Delivery/Rental/Purchase Agreement signed by the Account Manager and the patient at the appointment on January 31, 2011 confirms that the patient was not only fitted for the knee brace ordered by the physician, but also ended up with a "RS-OA Knee System Stimulator" that was not on the doctor's original order.

38. Defendant's Account Manager also instructed the Relator that if she needed to make a change or correction to a prescription, she should go ahead and make the alterations by whiting out the original information, making the change, and "scribbl[ing] on the form beside the change" to make it look like the physician's initials. Because the Relator was uncomfortable with RS Medical's practice of altering physician orders, she repeatedly feigned ignorance as to how to alter the records. On December 13, 2011, the Defendant's Account Manager e-mailed the Relator offering to "fix the notes" for her.

39. On information and belief, the Defendant systematically engages in fraud in the renewal of certain devices such as TENS units. Medicare regulations require that "[w]hen used for the treatment of chronic, intractable pain, the TENS unit must be used by the patient on a trial basis for a minimum of one month (30 days), but not to exceed two months. The trial period will be paid as a rental. The trial period must be monitored by the physician to determine the effectiveness of the TENS unit in modulating pain."

40. On information and belief, after the trial period, Medicare may approve the sale of a TENS unit but "[f]or coverage of a TENS purchase, the physician must determine that the patient is likely to derive significant therapeutic benefit from the continuous use of the unit over a long period of time. The physician's records must document a reevaluation of the patient at the end of the trial period, must indicate how often the patient used the TENS unit, the typical duration of use each time, and the results."

41. On information and belief, the Defendant's "RS-LB™ Low Back Conductive Garment" is governed by Medicare's regulations concerning TENS units.

42. On information and belief, the Defendant has all post 30-day renewals and sales handled by the Account Manager. The Defendant routinely processes orders for the renewal and sale of TENS units, low back garments, and other pain relief devices without proper physician authorization through the same scheme described above.

43. In addition, the Defendant has also instructed the Relator to ignore the 30-day waiting period and provide a low back garment to a patient who had not even been seen by the physician for his follow-up. By way of example, on December 9, 2010, the Defendant's Account Manager e-mailed the Relator discussing a patient who would like to receive a low back garment prior to his follow-up visit with the physician. The Account Manager instructs the Relator as follows: "his next appt is 1-24-11 which is fine and I can do renewal then. The medicare guidelines require us by law to wait til then to give him his lbg [Low Back Garment], but if you want to send him one to go ahead and be using just so we can help him now, then go ahead and do that….Let him know because he is so sweet and you want to help him that it[']ll just be your and his secret but you[']re gonna go ahead and send him the garment to him yourself…that his appt on January 24th is his next appt so no need to make one before that to just keep that appt. and to be sure and tell the doctor the TENS unit is really helping with NO mention of the LBG."

44. On information and belief, only after the Relator repeatedly complained did the company agree to investigate. After the internal investigation was begun, however, the company attempted to cover up the fraudulent activity by shredding the blank prescription forms.

VIOLATION OF THE FEDERAL FALSE CLAIMS ACT

45. Relator realleges and incorporates by reference the allegations made in paragraphs 1 – 44 of this Complaint. This is a claim for treble damages and forfeitures under the False Claims Act, 31 U.S.C. §§ 3729-3732, as amended.

46. Through the acts described above, Defendant and its agents and employees knowingly presented and caused to be presented to the United States Government false and fraudulent claims, records, and statements in order to obtain reimbursement for health care services provided under Medicare, Medicaid, TRICARE and other government-funded health insurance plans.

47. Through the acts described above and otherwise, Defendant and its agents and employees knowingly made, used, and/or caused to be made or used false records and statements in order to get such false and fraudulent claims paid and approved by the United States Government.

48. Through the acts described above and otherwise, Defendant and its agents and employees knowingly made, used, and/or caused to be made or used false records and statements to conceal, avoid, and/or decrease Defendant's obligation to repay money to the United States Government that Defendant improperly and/or fraudulently received. Defendant also failed to disclose to the United States Government material facts that would have resulted in substantial repayments by it to the federal government.

49. The United States, its fiscal intermediaries, and the Medicaid program, unaware of the falsity of the records, statements, and claims made or submitted by Defendant and its agents and employees paid and continue to pay Defendant for claims that would not be paid if the truth were known.

50. The United States, its fiscal intermediaries, and the Medicaid program, unaware of the falsity of the records, statements, and claims made or submitted by Defendant and its agents and employees – or of their failure to disclose material facts which would have reduced government obligations – have not recovered Medicare and Medicaid funds that would have been recovered otherwise.

51. By reason of the Defendant's false records, statements, claims, and omissions, the United States has been damaged in paying fraudulent claims with Medicare and Medicaid funds.

52. The False Claims Act provides that the Relator may be entitled to reasonable attorneys' fees, and Relator demands those fees and such other damages to which she or the United States may be entitled.

PRAYER

WHEREFORE, Plaintiff/Relator prays for judgment against the Defendant as follows:

(1) That Defendant cease and desist from violating 31 U.S.C. § 3729 *et seq.*;

(2) That the Court enter judgment against Defendant in an amount equal to three times the amount of damages the United States has sustained as a result of Defendant's actions, as well as a civil penalty of $11,000 for each violation of 31 U.S.C. § 3729;

(3) That Plaintiff/Relator be awarded the maximum amount allowed pursuant to section 3730(d) of the FCA;

(4) That Plaintiff/Relator be awarded the maximum amount allowed pursuant to section 3730(h) of the FCA, including two times the amount of back pay, litigation costs, and reasonable attorneys' fees;

(5) That Plaintiff/Relator be awarded all costs and expenses of this action, including attorneys' fees; and

(6) That the United States and Plaintiff/Relator receive all such other relief as the Court deems just and proper.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff hereby demands trial by jury.

WYCHE, BURGESS, FREEMAN & PARHAM, PA

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February 14, 2011